APR 22 2009

510(k) Summary: AVS® AL PEEK Spacers

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Vikki M. O'Connor Regulatory Consultant Phone: 201-760-8215 FAX: 201-760-8415 Email: vikki.o'connor@stryker.com
Date Prepared	January 12, 2009
Trade Name	Stryker Spine AVS® AL PEEK Spacers
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR 888.3080
Product Code	MAX
Predicate Devices	Stryker Spine AVS® PL PEEK Spacers: K073470 Pillar XL Peek Spacers: K082235 DePuy AcroMed, Inc. Lumbar I/F Cage® (i.e., Brantigan Cage) with VSP Spine System: P960025.
Device Description	The AVS® AL Peek Spacers are intervertebral body fusion devices intended for use as an aid in spinal fixation. The Stryker Spine AVS® AL PEEK Spacer is a ring shaped, hollow frame implant with lateral fenestrations, machined from medical grade PEEK OPTIMA™ LT1 that is radiolucent and incorporates three (3) Tantalum marker pins to aid in radiographic visualization. The upper and lower aspects of the subject device are open, and the superior and inferior surfaces have serrations that assist in the anchorage and seating of the device.

	The subject devices are manufactured out of the following materials: • Spacers: Polyetheretherketone (PEEK) OPTIMA™ LT1 (ASTM F2026) • Marker Pins: Tantalum (ASTM F560). The Stryker Spine AVS™ AL PEEK Spacer family is comprised of six (6) different heights (10, 12, 14, 16, 18 and 20mm), two (2) lengths (22 mm and 28 mm), two (2) widths (28 mm and 33 mm) and lordotic angles of 4° and 8 °, which allows the surgeon to best choose the size suited to the patient's anatomy and pathology. (Implant drawings and part numbers can be found in **Section 11** of this application).
Intended Use	The Stryker Spine AVS® AL PEEK Spacers are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. The AVS® AL PEEK Spacers are to be implanted via an anterior or anterolateral approach. The AVS® AL PEEK Spacers are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and

	rod systems).
Summary of the Technological Characteristics	Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS® AL PEEK Spacers and demonstrated substantial equivalent performance characteristics to the identified predicate device systems. Testing Reports can be found in Section 18 of this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Spine
% Ms. Vikki O'Connor
Regulatory Consultant
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Allendale, New Jersey 07401

APR 22 2009

Re: K090166
Trade/Device Name: Stryker Spine AVS® AL PEEK Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: January 21, 2009
Received: January 22, 2009

Dear Ms. O'Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090166

Device Name: Stryker Spine AVS® AL PEEK Spacers

Indications For Use:

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DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The AVS® AL Peek Spacers are to be implanted via an anterior or anterolateral approach.

The AVS® AL PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090166